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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/254,407 | 02/07/00 | GRADY | JJM-399 |

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EXAMINER

WHITE, E

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/254,407

Applicant(s)
GRADY et al.

Examiner
Everett White

Group Art Unit
1623



☒ Responsive to communication(s) filed on Dec 8, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above, claim(s) 12-14 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-10 is/are rejected.

☒ Claim(s) 11 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Amendment A filed December 8, 2000 has been received and entered into the record.
2. Claims 1-14 are pending in the case.
3. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

Rule 126 - Renumbered Claims

4. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 14-16 been renumbered 12-14.

Election by Original Presentation

5. Newly submitted claims 12-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 12 and 13 are directed to a method of treating a medical condition mediated by matrix metalloproteinase and is limited to the use of composition to treat the medical condition which is distinct from the method recited in the original pending claims which uses a sulfated polysaccharide compound to treat wounds. Claim 14 is also distinct from the original claims since claim 14 is directed to a method for the prevention or reduction of blood coagulation by administering a pharmaceutical composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 12-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

35 U.S.C. 112, 2nd Paragraph/35 U.S.C. 101 Rejection
Improper Use Claims

6. Claims 1-11 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1-11 provides for the use of a sulfated polysaccharide selected from the group consisting of sulfated cellulose derivatives and sulfated polyanionic polysaccharides for the preparation of the treatment of a chronic wound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

7. Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

8. Applicant's arguments filed December 8, 2000 have been fully considered but they are not persuasive. Applicants argue that Claims 1-11 are directed to compositions and request clarification of the rejection. A copy of Claims 1-11 that are pending in the instant application are attached to the instant Office action. No properly disclosed preliminary amendment was noted in the instant application. The rejection of Claim 1-11 as improper use claims is maintained.

IMPROPER MULTIPLE DEPENDENT CLAIMS

9. Claim 11 stand objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

10. Applicant's arguments filed December 8, 2000 have been fully considered but they are not persuasive. Applicants amendment to claims 8, 9 and 10 to over come the objection of the claims for being in improper form because of a multiple dependent claim have been entered. However, there was no amendment to Claim 11. The objection to Claim 11 as being in improper form because of a multiple dependent claim is maintained.

35 U.S.C. 103 REJECTION

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Easton (EP 140,596) and Spilburg et al (US Patent No. 5,679,375) in view of Tunc (US Patent No. 3,939,836).

Applicants claim the use of a synthetic sulfated polysaccharide selected from the group consisting of sulfated cellulose derivatives and sulfated polyanionic polysaccharides for the preparation of a composition for the treatment of a chronic wound.

The Easton et al reference discloses a wound dressing having a wound contacting layer form from a complex that includes a biodegradable protein, or a proteolytic degradation product thereof, with a polyanionic plant polysaccharide. Easton et al further discloses that a surgical implant can be formed from the complex. Easton disclosed that the term "surgical implant" includes sutures, blood vessel grafts, artificial organs, soft tissue implants and prostheses (see page 2, 1st paragraph). Examples of the polyanionic plant polysaccharides disclosed in the Easton et al reference include alginates, carrageenans, celluloses such as carboxymethyl cellulose, xanthan gum and sulphate dextrans (see page 4, lines 21-34). Also see page 1, second paragraph of the

Easton et al reference which sets forth a number of polyanionic polysaccharides that are well known in the art to be useful in a wide variety of medical and surgical applications which include hyaluronic acid, chondroitin 4-sulphate, chondroitin 6-sulphate, dermatan sulphate, keratan sulphate and heparan sulphate. The instant invention differ from the above description of a wound dressing having a wound contacting layer form from a complex that comprises a polyanionic plant polysaccharide by indicating that the polysaccharides are synthetic sulfated polysaccharides. However, the sulfation of polysaccharides is well known in the art. For example, see column 3, lines 18-38 of the Tunc patent wherein a well known procedure for preparing sulfated cellulose is disclosed. The Tunc patent shows that the use of sulfated cellulose in wound dressings is well known in the art. It would have been obvious to modify the polyanionic polysaccharides of the Easton et al reference by subjecting the polysaccharides thereof, to a sulfated procedure as taught by the Tunc patent, since the Tunc patent suggests at column 3, last paragraph, that by modifying the degree of sulfate substitution of the polysaccharide, the salt resistance and water dispersibility of the bonded nonwoven fabric (when the polysaccharide is used in the form of a fabric) can be modified to provide fabrics which will function effectively when contacted by various body fluids - which may be flushed away in a water closet.

13. Applicant's arguments with respect to Claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

State of the Art

14. The Lange, III et al patent (US Patent No. 5,017,565) which shows that the sulfation of polysaccharides such as alginic acid, pectin, chitin, dextrans, and cellulose to produce sulfated derivatives is well known in the art (see column 2, last paragraph) is cited to further show the state of the art.

15. **Summary:** Claims 1-10 are rejected; Claim 11 is objected to; and Claims 12-14 are withdrawn from consideration.

Office Action Made Final

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Examiner's Telephone Number, Fax Number, and Other Information

17. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


White
March 6, 2001


GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600

CLAIMS

1. Use of a ^{synthetic} sulfated polysaccharide selected from the group consisting of sulfated cellulose derivatives and sulfated polyanionic polysaccharides for the preparation of a composition for the treatment of a chronic wound.
2. Use according to claim 1, wherein the sulfated polysaccharide is selected from the group consisting of sulfated hydroxyethyl cellulose, sulfated carboxymethyl cellulose and sulfated oxidized regenerated cellulose.
3. Use according to claim 2, wherein the sulfated polysaccharide is sulfated oxidized regenerated cellulose.
4. Use according to claim 1, wherein the sulfated polysaccharide is selected from the group consisting of sulfated alginates, sulfated pectins and sulfated hyaluronic acid.
5. Use according to claim 4, wherein the sulfated polysaccharide is a sulfated alginate.
6. Use according to any preceding claim, wherein the sulfated polysaccharide comprises an average of at least 0.1 sulfate groups for each saccharide residue of the polysaccharide.
7. Use according to claim 6, wherein the sulfated polysaccharide comprises an average of at least 1 sulfate group for each saccharide residue of the polysaccharide.
8. Use according to ^{claim 1} ~~any preceding claim~~, wherein the sulfated polysaccharide has an average molecular weight in the range 25,000 to 250,000.
9. Use according to ^{claim 1} ~~any preceding claim~~, wherein the sulfated polysaccharide is in the form of a woven, non-woven or knitted fabric.

10. Use according to ^{claim}~~any preceding claim~~, wherein the sulfated polysaccharide is in the form of a solid complex with collagen.

11. Use according to any preceding claim, wherein the sulfated polysaccharide is
5 soluble in water to an extent of at least 10 g/l at 25°C.

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